

## REMARKS/ARGUMENTS

The foregoing amendments in the specification serve to correct obvious typographical errors and insert SEQ ID NOs at appropriate locations, as requested in the Office Action. The claim amendments are of formal nature, and serve to present the claims in better form for examination and/or address issues raised in the Office Action. Both the amendments in the specification and the claim amendments are fully supported by the disclosure as originally filed, and do not add new matter.

Prior to the present amendment, claims 1-50 were pending in this application. Claims 6-8, 28-34, 36, 37, 39-48 and 50 have been withdrawn from consideration, and claims 1-5, 9-27, 35, 38 and 49 have been rejected on various grounds.

### *The Restriction Requirement*

Applicants were requested to elect, for examination purposes, one of Groups I-VIII listed on page 2 of the Office Action. The Examiner noted that if product claims are elected, and the elected product claims are subsequently allowable, process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if presented prior to final rejection or allowance. After such rejoinder, the restriction requirement between the product claims and such process claims will be withdrawn, and the process claims will be fully examined for patentability.

The oral election of the Claims of Group I (claims 1-5, 9-27, 35, 38, and 49), drawn to IGF-1 crystal and method of making, is hereby affirmed.

Applicants submit that all additional remaining process claims have been amended to depend from or otherwise include all the limitations of the current product claims. Accordingly, upon finding the elected Group I claims patentable, claims 6, 7, 8, 36, 39-48 and 50 should be rejoined with the elected product claims, and fully examined on their merits.

**Objection to the Disclosure**

The disclosure has been objected to since it contained references to specific amino acid residues without identifying the amino acid sequence(s) with a sequence identifier number.

The foregoing amendments to the specification are believed to adequately address this objection.

**Rejections under 35 U.S.C. §112, first paragraph**

(1) Claims 1-5, 9-27, 35, 38, and 49 have been rejected as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has acknowledged that the specification provides written description for human IGF-1 of SEQ ID NO: 1 in orthorhombic crystals having the space Group of C222<sub>1</sub> with cell unit dimensions  $a=31.831 \text{ \AA}$ ,  $b=71.055 \text{ \AA}$ ,  $c=65.995 \text{ \AA}$ , and  $\alpha=\beta=\gamma=90^\circ$ , and noted that the insertion of SEQ ID NO: 1 in claim 2 would obviate this rejection with regard to claim 2.

Without acquiescing to the present rejection or the reasoning underlying the rejection, claim 1 has been canceled, and claim 2 has been rewritten in independent form including a reference to SEQ ID NO: 1. Accordingly, the present rejection with regard to claim 2 and all claims dependent on claim 2 or otherwise carrying the limitations of claim 2 should be withdrawn.

With regard to process claims 9 and 10, the Examiner additionally noted that the specification teaches crystallization of IGF-1 crystals having the space Group of C222<sub>1</sub> with cell unit dimensions  $a=31.831 \text{ \AA}$ ,  $b=71.055 \text{ \AA}$ ,  $c=65.995 \text{ \AA}$ , and  $\alpha=\beta=\gamma=90^\circ$  under

conditions described in the paragraph bridging pages 18 and 10 of the specification. Claim 9 has been amended to include such conditions, and claim 10, being dependent on claim 9, carries the same recitations.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

(2) Claims 1-5, 9-27, 35, 38, and 49 have been rejected as, according to the Examiner, the specification is enabling only for claims limited to orthorhombic crystals of IGF-1 having the space Group of  $C222_1$  with cell unit dimensions  $a=31.831 \text{ \AA}$ ,  $b=71.055 \text{ \AA}$ ,  $c=65.995 \text{ \AA}$ , and  $\alpha=\beta=\gamma=90^\circ$  under the conditions described in the paragraph bridging pages 18 and 10 of the specification.

Without acquiescing to the present rejection, all claims have been amended as suggested by the Examiner. Accordingly, the present rejection should be withdrawn.

**Rejections under 35 U.S.C. §112, second paragraph**

Claims 1-5, 9-27, 35, 38 and 49 have been rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

(a) Claims 1, 5, 9, 27, 35, 38 and 49 have been rejected for containing the undefined acronym "IGF-1." The current claim amendments, which introduce the full name (insulin-like growth factor-1) into each independent claim, moot this rejection.

(b) The phrase "crystal with the structure coordinates shown in Appendix 1" has been objected to in claim 38. Since Claim 38 has been amended as suggested by the Examiner, this rejection is moot.

(c) Claims 2-4 and 10-26 were included in this rejection as a result of their dependency on rejected claims. Claim 2 has been rewritten in independent form, and all

independent claims have been revised to address the issues raised in the present rejection. Accordingly, the rejection of the dependent claims should also be withdrawn.

**Information Disclosure Statement**

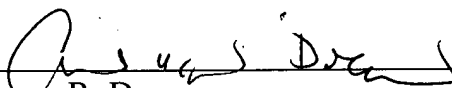
In the initialed PTO-1449 Form attached to the present Office Action, several referenced have been crossed out, as apparently missing from the Office file. A Supplemental Information Disclosure Statement, listing and enclosing the references not considered, accompanies the present Amendment and Response. The Examiner is respectfully requested to confirm consideration of the currently submitted references by returning an initialed copy of the attached PTO-1449 form.

Applicants appreciate the Examiner's comment that the claims are free of prior art and that claims directed to a specific crystal comprising SEQ ID NO: 1 and a specific method of making such crystal would be considered favorably. It is believed that the current claims are directed to such subject matter, and should therefore be allowed.

Should the Examiner find that there are any further issues outstanding, he is respectfully invited to contact the undersigned attorney at the telephone number indicated below in order to arrange a personal interview, before issuance of a further Office Action.

Respectfully submitted,

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